

The ITEQ comprises 28 items with the subscales 'leisure activities' (4 items), 'psychological barriers' (2 items), 'handling' (5 items), 'diabetes control' (6 items), 'dependence' (5 items), 'weight control' (3 items), 'sleep' (2 items) as well as one item assessing general TS. First results demonstrated good psychometric properties. The aim of the present paper was to compare the performance of the ITEQ and DTSQ in discriminating patients TS in different insulin therapies. **METHODS:** A sample of T2DM patients ($n = 150$) completed the ITEQ and DTSQ. TS as assessed by the instruments was compared between respondents with different insulin regimens (intensified insulin therapy, $n = 70$; OAD plus insulin, $n = 47$; longacting insulin only, $n = 33$) using analysis of variance (ANOVA). **RESULTS:** While ITEQ subscales (diabetes control, dependence, weight control, sleep) and the total score revealed significant differences in patients TS between therapy regimens ($p < 0.001$), results for the DTSQ score were only marginally significant ($p = 0.154$). Furthermore different patterns for ITEQ subscales were observed even for variants of insulin therapy within one type of regimen. **CONCLUSION:** Comparisons with an existing measurement suggest that the ITEQ performs well in discriminating TS levels in patients undergoing diabetes treatment. The content of the ITEQ subscales provide important information about specific aspects of patients TS in insulin treatment. In the near future, the ITEQ will be translated into other languages.

PDB79

THE DIABETES MEDICATION SATISFACTION TOOL (DMSAT): DEVELOPMENT AND VALIDATION OF A NEW PATIENT-CENTERED OUTCOMES INSTRUMENT FOR CLINICIANS

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OBJECTIVES: As an aid to diabetes clinical care and research we sought to develop a valid and reliable instrument: the Diabetes Medication Satisfaction Tool (DMSAT) to measure patient satisfaction with a broad spectrum of diabetes treatment regimens in primary care. This was a cross-sectional survey study to develop and test a self-report questionnaire on satisfaction with diabetes medications. **METHODS:** Item content was obtained from focus groups of patients attending community health clinics, pre-tested in a sample of 55 patients with Type 2 diabetes, and examined in a sample of 140 patients of a group family practice with a diagnosis of diabetes and prescribed medical therapy. Factor analysis and tests of subscale and total score means across clinical groups were used to examine measurement characteristics. **RESULTS:** Sixteen items were retained assessing four distinct medication treatment experiences: ease and convenience, lifestyle burdens, well-being, and medical control. Construct validity of the scales and total score were demonstrated by statistically significant ($p < 0.05$) associations with treatment complexity, follow-up visits, self-rated glucose control, health worries, and A1c in the last six months. Internal consistency reliability coefficients for the scales and total score ranged from 0.89 to 0.95. **CONCLUSION:** The results of this study suggest that the DMSAT has good construct validity and reliability, and is sensitive to levels of clinical and patient reported outcomes that relate to treatment burden and Type II diabetes control. The DMSAT offers a comprehensive assessment of the patient acceptability and satisfaction with the use of diabetes medication therapy in their daily life. Testing across two independent patient samples showed DMSAT scores correspond to clinically relevant outcomes.

ENDOCRINE DISORDERS—Methods and Concepts

PENI

TIME-AND-MOTION EVALUATION OF DIFFERENT GROWTH HORMONE FORMULATIONS

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OBJECTIVES: To compare the number of steps, associated time and costs related to administration of human growth hormone (hGH) via different devices using time-and-motion simulations. Previously all hGH formulations required reconstitution of lyophilized powder and transfer to syringe prior to administration. With the development of a liquid formulation of hGH, premixed and prefilled disposable devices are now available. Daily compliance may depend upon "ease of use" characteristics across various product and device combinations. Also, the additional time required to prepare devices which are not available with premixed product may result in increased costs from professional and patient perspectives. **METHODS:** It is assumed the users attend 1 training session, prepare 1 preparation per week, and administer the drug three or seven times per week depending on the product labeling specifications. This study simulates 3 phases: Learning (initial instructions for use), Preparation (opening a new package and making the device ready for use), and Administration (the actual injection of either the first dose or subsequent doses). Nurses without prior experience with the application of hGH or similar drug-device combinations are, after the initial training session, running 5 series of preparations, initial administrations, and follow-up dose administrations to reflect the learning curves in the respective steps. Costs will include wages (Bureau of Labor Statistics) and drugs (First Data-bank). **RESULTS:** This study design provides a unique method to compare the learning curves for the different product/device combinations, and to compare the relative time needed for preparation and administration. The validated methods and preliminary results will be part of the presentation. **CONCLUSION:** This time and motion study protocol, allows for comparing the number of steps and the overall time required for preparation and application of hGH in various devices and can be applied to self injectable product comparisons in general.

HEMATOLOGICAL DISORDERS—Clinical Outcomes Studies

PHMI

ASSESSING PATIENTS' RISKS OF BLOOD TRANSFUSIONS: A LITERATURE REVIEW OF PUBLISHED INCIDENCE RATES

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OBJECTIVES: Through a literature review, evaluate the incidence rates of different adverse events associated with blood transfusions among the general population. **METHODS:** A structured, 2-phase literature review was conducted using the PubMed (National Library of Medicine) database to search for articles quoting incidence rates of adverse reactions associated with blood transfusions. The first phase of the literature review looked for general blood transfusion risk studies reported during the time period of 1985 to 2007 to identify adverse events associated with blood transfusions. The second phase of the literature review, looking at studies reported 2000 to 2007, assessed incidence rates for each adverse event identified during the first phase. The search generated 41 articles from which data